

703 308 4242;# 5
Duplicate

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**For: URINARY TUMOR ASSOCIATED
ANTIGEN, ANTIGENIC SUBUNITS
AND METHODS OF DETECTION**

2025 2024 2023 2022 2021 2020 2019 2018 2017 2016 2015 2014 2013 2012 2011 2010 2009 2008 2007 2006 2005 2004 2003 2002 2001 2000 1999 1998 1997 1996 1995 1994 1993 1992 1991 1990 1989 1988 1987 1986 1985 1984 1983 1982 1981 1980 1979 1978 1977 1976 1975 1974 1973 1972 1971 1970 1969 1968 1967 1966 1965 1964 1963 1962 1961 1960 1959 1958 1957 1956 1955 1954 1953 1952 1951 1950 1949 1948 1947 1946 1945 1944 1943 1942 1941 1940 1939 1938 1937 1936 1935 1934 1933 1932 1931 1930 1929 1928 1927 1926 1925 1924 1923 1922 1921 1920 1919 1918 1917 1916 1915 1914 1913 1912 1911 1910 1909 1908 1907 1906 1905 1904 1903 1902 1901 1900 1899 1898 1897 1896 1895 1894 1893 1892 1891 1890 1889 1888 1887 1886 1885 1884 1883 1882 1881 1880 1879 1878 1877 1876 1875 1874 1873 1872 1871 1870 1869 1868 1867 1866 1865 1864 1863 1862 1861 1860 1859 1858 1857 1856 1855 1854 1853 1852 1851 1850 1849 1848 1847 1846 1845 1844 1843 1842 1841 1840 1839 1838 1837 1836 1835 1834 1833 1832 1831 1830 1829 1828 1827 1826 1825 1824 1823 1822 1821 1820 1819 1818 1817 1816 1815 1814 1813 1812 1811 1810 1809 1808 1807 1806 1805 1804 1803 1802 1801 1800 1799 1798 1797 1796 1795 1794 1793 1792 1791 1790 1789 1788 1787 1786 1785 1784 1783 1782 1781 1780 1779 1778 1777 1776 1775 1774 1773 1772 1771 1770 1769 1768 1767 1766 1765 1764 1763 1762 1761 1760 1759 1758 1757 1756 1755 1754 1753 1752 1751 1750 1749 1748 1747 1746 1745 1744 1743 1742 1741 1740 1739 1738 1737 1736 1735 1734 1733 1732 1731 1730 1729 1728 1727 1726 1725 1724 1723 1722 1721 1720 1719 1718 1717 1716 1715 1714 1713 1712 1711 1710 1709 1708 1707 1706 1705 1704 1703 1702 1701 1700 1699 1698 1697 1696 1695 1694 1693 1692 1691 1690 1689 1688 1687 1686 1685 1684 1683 1682 1681 1680 1679 1678 1677 1676 1675 1674 1673 1672 1671 1670 1669 1668 1667 1666 1665 1664 1663 1662 1661 1660 1659 1658 1657 1656 1655 1654 1653 1652 1651 1650 1649 1648 1647 1646 1645 1644 1643 1642 1641 1640 1639 1638 1637 1636 1635 1634 1633 1632 1631 1630 1629 1628 1627 1626 1625 1624 1623 1622 1621 1620 1619 1618 1617 1616 1615 1614 1613 1612 1611 1610 1609 1608 1607 1606 1605 1604 1603 1602 1601 1600 1599 1598 1597 1596 1595 1594 1593 1592 1591 1590 1589 1588 1587 1586 1585 1584 1583 1582 1581 1580 1579 1578 1577 1576 1575 1574 1573 1572 1571 1570 1569 1568 1567 1566 1565 1564 1563 1562 1561 1560 1559 1558 1557 1556 1555 1554 1553 1552 1551 1550 1549 1548 1547 1546 1545 1544 1543 1542 1541 1540 1539 1538 1537 1536 1535 1534 1533 1532 1531 1530 1529 1528 1527 1526 1525 1524 1523 1522 1521 1520 1519 1518 1517 1516 1515 1514 1513 1512 1511 1510 1509 1508 1507 1506 1505 1504 1503 1502 1501 1500 1499 1498 1497 1496 1495 1494 1493 1492 1491 1490 1489 1488 1487 1486 1485 1484 1483 1482 1481 1480 1479 1478 1477 1476 1475 1474 1473 1472 1471 1470 1469 1468 1467 1466 1465 1464 1463 1462 1461 1460 1459 1458 1457 1456 1455 1454 1453 1452 1451 1450 1449 1448 1447 1446 1445 1444 1443 1442 1441 1440 1439 1438 1437 1436 1435 1434 1433 1432 1431 1430 1429 1428 1427 1426 1425 1424 1423 1422 1421 1420 1419 1418 1417 1416 1415 1414 1413 1412 1411 1410 1409 1408 1407 1406 1405 1404 1403 1402 1401 1400 1399 1398 1397 1396 1395 1394 1393 1392 1391 1390 1389 1388 1387 1386 1385 1384 1383 1382 1381 1380 1379 1378 1377 1376 1375 1374 1373 1372 1371 1370 1369 1368 1367 1366 1365 1364 1363 1362 1361 1360 1359 1358 1357 1356 1355 1354 1353 1352 1351 1350 1349 1348 1347 1346 1345 1344 1343 1342 1341 1340 1339 1338 1337 1336 1335 1334 1333 1332 1331 1330 1329 1328 1327 1326 1325 1324 1323 1322 1321 1320 1319 1318 1317 1316 1315 1314 1313 1312 1311 1310 1309 1308 1307 1306 1305 1304 1303 1302 1301 1300 1299 1298 1297 1296 1295 1294 1293 1292 1291 1290 1289 1288 1287 1286 1285 1284 1283 1282 1281 1280 1279 1278 1277 1276 1275 1274 1273 1272 1271 1270 1269 1268 1267 1266 1265 1264 1263 1262 1261 1260 1259 1258 1257 1256 1255 1254 1253 1252 1251 1250 1249 1248 1247 1246 1245 1244 1243 1242 1241 1240 1239 1238 1237 1236 1235 1234 1233 1232 1231 1230 1229 1228 1227 1226 1225 1224 1223 1222 1221 1220 1219 1218 1217 1216 1215 1214 1213 1212 1211 1210 1209 1208 1207

Atty. Dkt.: CADL:002/PAR

GROUP 1800

Steven L. Highlander

DECLARATION OF RALPH A. REISEFELD UNDER 37 C.F.R. §1.132

1. I am Head of the Division of Tumor Cell Biology at the Scripps Research Institute, La Jolla, CA. I have held this position for 26 years. A copy of my *curriculum vitae* is already of record.

BEST AVAILABLE COPY

2. I have reviewed the abstract of Euhus *et al.*, 24th Annual Meeting of the American Society of Clinical Oncology Proceedings, May 22-24, 1988, and the claims pending in the above-captioned application. It is my understanding that the examiner in charge of the above-captioned application has alleged that the Euhus abstract is relevant to the patentability of the subject matter of the instant application.

3. The Euhus abstract merely relates to an antigen designated U-TAA. Yet, the abstract does not provide any information that would permit those of skill in the art to confirm that a given antigen, if isolated, was or was not the U-TAA of the abstract. Specifically, the Euhus abstract only identifies U-TAA as existing in IgG and IgM fractions in the serum of some melanoma patients, provides its predicted molecular mass and asserts that the antigen contains at least four subunits of varying molecular mass. It does not, however, provide any information on the amino acid sequence of this molecule. Thus, a meaningful description of this molecule is not provided by the abstract. Without such information, those of skill in the art would not know if they had isolated what Euhus *et al.* had designated as U-TAA.

4. Similarly, the Euhus *et al.* abstract is devoid of any information regarding the immunologic identity of the antigen. Though a murine antibody that binds U-TAA is mentioned, this antibody is neither described nor was it publicly available at the time the instant application was filed. Moreover, the method by which the murine antibody was produced (e.g. antigen composition, immunization regimen, selection criteria) is not described. Without such

information, those of skill in the art would not have had the Euhus antibody, much less been able to use it to determine if they had isolated what Euhus *et al.* had designated as U-TAA.

5. Therefore, based on my 40 years of experience in the isolation, purification and characterization of biological products similar to U-TAA, reproduction of the work described in the Euhus *et al.* abstract would have relied, almost entirely, on an empirical "trial and error" approach, and thus would have lacked any reasonable and reliable expectation of success from its inception. Even if those of skill in the art would have fortuitously reproduced the work described in the Euhus *et al.* abstract, they could not have confirmed such a success with the information available.

6. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful, false statements may jeopardize the validity of this application or any patent issued thereon.

Date

11/26/96


Ralph A. Reisfeld, Ph.D.